Section 1. Human Research Protection Program

Western Michigan University Homer Stryker M.D. School of Medicine fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted at, under the auspices of, or using the services or resources of the medical school. In the review and conduct of research, actions by the medical school are guided by the principles set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*: respect for persons, beneficence, and justice. The actions of the medical school also conform to all applicable federal, state, and local laws and regulations. In order to fulfill this mission, the medical school has established a Human Research Protection Program (HRPP). The medical school HRPP, in collaboration with its research community, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted at, under the auspices of, or using the services or resources of the medical school. This includes research that is externally funded, funded from internal sources, or conducted without direct funding.

1.1 Mission

The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected.
- Provide guidance and support to the research community in the conduct of research with human subjects.
- Assist the research community in ensuring compliance with relevant federal, state, and local laws and regulations.
- Provide timely and high quality education, review, and monitoring of human research projects.
- Facilitate excellence in human subjects research.

The HRPP implements procedures to:

- Monitor, evaluate, and continually improve the protection of human research participants.
- Dedicate resources sufficient to do so.
- Exercise oversight of human subjects research, and protection of research participants.
- Educate investigators and research staff about their ethical responsibility to protect research participants.
- When appropriate, intervene in research and respond directly to concerns of research participants.

1.2 Organizational Authority

The medical school HRPP operates under the authority of the medical school. The *Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook* serves as the governing policies and procedures for the conduct and review of all human research conducted at, under the auspices of, or using the services or resources of the medical school. HRPP policies and these operating procedures are made available to all medical school investigators and research staff on the medical school website.

The medical school designates the dean of the medical school as the Institutional Official who has overall responsibility for the medical school HRPP. The duties of the Institutional Official include:

1. Fostering, supporting, and maintaining an organizational culture that promotes and facilitates the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies.
2. Ensuring that the Institutional Review Board (IRB) functions independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and members if they experience undue influence or if they have concerns about the function of the IRB.
3. Oversight of the Institutional Review Board (IRB).
4. Oversight of the conduct of research conducted by all medical school investigators.
5. Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations.
6. Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations.
7. Oversight of the development and implementation of an educational plan for IRB members, staff, and investigators.
8. Ensuring compliance with institutional policies and all applicable regulations for the protection of human subjects.
9. Serving as the signatory authority and ensuring compliance with the terms of the Federalwide Assurance to the Office of Human Research Protections (OHRP).
10. Providing support to the HRPP by ensuring that the HRPP has sufficient staff and resources to fulfill its role and obligations.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, the medical school maintains an IRB to review research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the medical school. The IRB has the following authority:

- To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the medical school, regardless of location of the research activities.

- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information in addition to that specifically stated in the regulations be provided to subjects when, in the judgment of the IRB, the information would meaningfully add to the protection of the rights and welfare of subjects.
- To conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year.
- To suspend or terminate approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.
- To observe, or have a third party observe, the consent process.
- To observe, or have a third party observe, the conduct of the research.
- To determine, with the assistant dean for Research Compliance, whether data or information gathered without IRB approval or in association with serious noncompliance may be published or used for research purposes. Both the IRB and the assistant dean for Research Compliance must approve the publication or use of such data or information.

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval of a study by the IRB lapses, all research activity for the study must stop immediately unless it is determined to be in the best interest of subjects who are already enrolled to continue participating in the research. The investigator can petition the IRB to continue an individual subject's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual subject to do so.

The HRPP has jurisdiction over all human subject research conducted under the auspices of the medical school, regardless of funding source or performance site. Research under the auspices of the institution includes research:

- Using any medical school facilities, property, services, or resources.
- Conducted by, with, or under the direction of any employee or agent of the medical school, including faculty and students, in connection with their medical school responsibilities.
- Involving the use of non-public information that is held by the medical school to identify, contact, or study human subjects.

Any research involving human subjects must be conducted with IRB approval. No research may commence until all required institutional approvals are obtained, including IRB approval if needed. Exempt research is subject to IRB review for determination of exemption status. At the medical school, exemptions are reviewed and granted by the IRB chair and vice chair. For medical school research not involving human subjects, review by the medical school IRB is not required. At the medical school, determinations of the need for IRB engagement are made by the IRB chair and vice chair.

At the discretion of the Institutional Official, the medical school may enter into an agreement to rely upon an IRB other than the medical school IRB or to enter into a joint review arrangement.

The Institutional Official may review any human subjects research protocol and has the authority to disapprove or terminate any research protocol that has been approved by the IRB. However, no one at the medical school shall approve or implement human subjects research that has not been approved by the IRB, and no one at the medical school shall approve or implement human subjects research by ignoring or overriding a decision of the IRB to disapprove or terminate a research protocol.

All institutional and non-institutional performance sites for the medical school, domestic or foreign, are obligated by this policy to conform to ethical principles that are at least equivalent to those of the medical school, or more stringent as may be determined by the Department of Health and Human Services (DHHS) Secretary.

The Institutional Official and IRB shall adopt operating procedures to implement this policy, which are in the *Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook*. These procedures shall serve as the governing procedures for the conduct and review of all human subjects research conducted under the auspices of the medical school, under the oversight of the medical school IRB, or using any medical school facilities, property, services, or resources.

1.3 Definitions

- **Common Rule**: The Common Rule refers to the "Federal Policy for the Protection of Human Subjects" adopted by a number of federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in . For the purposes of this document, references to the Common Rule cite the DHHS regulations.

- **Employee or Agent**: For the purposes of this document, *employees or agents* refers to individuals who: (1) act on behalf of the organization; (2) exercise organizational authority or responsibility; or (3) perform organizationally designated activities. Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

- **Engagement**: Department of Health and Human Services (DHHS) regulations [45 CFR 46.103[a]] require that an institution "engaged" in human subject research conducted or supported by a Federal Department or Agency provide the DHHS Office for Human Research Protection (OHRP) with a satisfactory assurance of compliance with the DHHS regulations, unless the research is exempt under 45 CFR 46.101(b). "In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them;

(2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research." Additionally, institutions that receive an award through a grant, contract, or cooperative agreement directly from DHHS for the non-exempt human subjects research (ie, awardee institutions), are also considered engaged in research even where all activities involving human subjects are carried out by employees or agents of another institution.

Human Subject: A human subject as defined by the Common Rule is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information [45 CFR 46.102(f)].

The terms "subject" and "participant" are used interchangeably in this document and have the same definition.

For research covered by FDA regulations, human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In research evaluating the safety or effectiveness of a medical device, a human subject also includes any individual on whose specimen an investigational device is used or tested or used as a control.

- **Human Subject Research**: Human Subject Research means any activity that meets the definition of "research" and involves "human subjects" as defined by the Common Rule, FDA regulations, or other applicable regulations.

- **Identifiable Information**: Identifiable information means information that is individually identifiable (ie, the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

- **Interaction**: An interaction means communication or interpersonal contact between investigator and subject.

- **Intervention**: An intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- **Private Information**: Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

- **Research**: The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or

contribute to generalized knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

For the purposes of this policy, a "systematic investigation" is an activity that involves a prospective study plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a study question. Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (ie, knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

The FDA has defined "research" as being synonymous with the term "clinical investigation." Clinical investigation, as defined by FDA regulations, means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR50.3(c), 21 CFR 56.102(c)]

Experiments that must meet the requirements for prior submission to FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act means any use of a drug other than the use of an approved drug in the course of medical practice. [21CFR321.3(b)]

Experiments that must meet the requirements for prior submission to FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act means any activity that evaluates the safety or effectiveness of a device. [21CFR812.2(a)]

Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21CFR50.3(c), 21CFR56.102(c)]

- **Test Article**: The FDA defines "Test article" as meaning any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act [42 U.S.C. 262 and 263b-263n]. [21CFR50.3(j)]

  Test articles covered under the FDA regulations include, but are not limited to:

- **Human drugs**: The primary intended use of the drug is achieved through chemical action or by being metabolized by the body. A drug is defined as a substance recognized by an official pharmacopoeia or formulary; a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; a substance (other than food) intended to affect the structure or any function of the body; a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process). *http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm*
- **Medical Devices**: A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm*
- **Biological Products**: Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources — human, animal, and microorganism — and may be produced by biotechnology methods and other new technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available. *http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm*
- **Food Additives**: A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not Generally Recognized As Safe (GRAS) or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.

http://www.fda.gov/Food/IngredientsPackagingLabeling/Definitions/default.htm

- **Color Additives**: A color additive is any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color. Color additives for use in food, drugs, and cosmetics require premarket approval. Color additives for use in or on a medical device are subject to premarket approval, if the color additive comes in direct contact with the body for a significant period of time. http://www.fda.gov/Food/IngredientsPackagingLabeling/Definitions/default.htm
- **Foods**: Foods include dietary supplements that bear a nutrient content claim or a health claim.
- **Infant Formulas**: Infant formulas are liquid foods intended for infants and substitute for mother's milk.
- **Electronic Products**: The FDA regulates certain classes of electronic products including radiation-emitting electronic products such as microwaves and x-rays.

1.4 Ethical Principles

The medical school is committed to conducting research with the highest regard for the welfare of human subjects. With the exception of transnational research, where consideration of alternative ethical principles may apply (see Section 25), the medical school upholds and adheres to the principles of *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979). These principles are:

- Respect for persons, which involves obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
- Beneficence, which involves ensuring that possible benefits are maximized and possible risks are minimized to all human subjects.
- Justice, which involves the equitable selection of subjects.

The medical school Human Research Protection Program (HRPP), in collaboration with its research community, is responsible for ensuring the ethical and equitable treatment of all human subjects in research conducted at, under the auspices of, or using the services or resources of the medical school.

1.5 Regulatory Compliance

The HRPP is responsible for ensuring compliance with federal regulations, state law and organizational policies. Human subjects research conducted at, under the auspices of, or using the services or resources of the medical school is conducted in accordance with applicable regulations and requirements of, but not limited to, the Common Rule, FDA, Health Insurance Portability and Accountability Act (HIPAA), U.S. Department of

Defense (DOD), U.S. Department of Education (DOE), U.S. Department of Justice (DOJ), and Family Educational Rights and Privacy Act (FERPA).
Research involving the use of Protected Health Information is reviewed and conducted in accordance with the (HIPAA), 45 CFR Part 160, 162, and 164.

Research supported by the DOD is reviewed and conducted in compliance with 32 CFR 219, 10 USC 980, applicable parts of title 21 CFR (50,56,312,600,812), DOD Instruction 3216.02, DOD Instruction 3210.07, and applicable additional requirements from respective DOD component(s). Researchers should consult the applicable DOD regulations, instructions, and directives when designing the research that may be supported by DOD. These rules include but are not limited to:

- Special education requirements for Navy-funded funded human subjects research.
- Appointment of research monitor for all research involving more than minimal risk to research participants.
- Special protections for U.S. military personnel participating in research.
- Disclosure and consent.
- Prohibition of research involving prisoners of war.

Review by the applicable DOD Human Research Protection Program and IRB may be required. The medical school will execute a DOD FWA or DOD Addendum to its FWA when required by the component of DOD that is involved. The IRB evaluates the research in accordance with these rules if applicable.

Research conducted or supported by the DOE is subject to the Common Rule with regulations published at 34 CFR 97. In addition to the Common Rule, human subjects research involving education records conducted at institutions receiving DOE funding must comply with additional requirements, including FERPA (34CFR99) and the Protection of Pupil Rights Amendment (PPRA) (34CFR98). Investigators should consult these regulations and resources provided by DOE when developing their research protocol. The Registrar serves as the medical school's FERPA Officer. The IRB evaluates the research in accordance with these regulations if applicable.

Research conducted or supported by the DOJ is subject to the Common Rule, including Subpart C, with regulations published at 28 CFR 46. The DOJ has established additional requirements for research conducted with the federal Bureau of Prisons (28 CFR 512), and research involving the National Institute of Justice (28 CFR 22). Investigators should consult these regulations and resources provided by NIJ when developing their research protocol. The IRB evaluates the research in accordance with these regulations if applicable.

1.6 International Conference on Harmonization-Good Clinical Practices (ICH-GCP)

When requested by an industry sponsor, the medical school will adhere to the International Conference on Harmonization of Technical Requirements for Registration

of Pharmaceuticals for Human Use Guideline for Good Clinical Practice, June 10, 1996 (sometimes referred to as "ICH-GCP E6"), for human subjects research involving pharmaceuticals. In general, the medical school applies ICH-GCP E6 guidelines only to the extent that they are compatible with DHHS and FDA regulations.

1.7 Federalwide Assurance (FWA)

The federal regulations require that federally conducted or supported human subject research only be conducted at facilities covered by a Federalwide Assurance (FWA) approved by the DHHS Office for Human Research Protections (OHRP). An FWA is an organization's assurance to the federal government that human subject research conducted at that site is in compliance with ethical principles and federal regulations pertaining to the protection of human subjects.

The medical school has an OHRP-approved Federalwide Assurance (FWA00009755) and has designated an internal IRB (registered as IRB00010682) to review human research conducted under its auspices.

In its FWA, the medical school has opted to limit the application of the FWA to non-exempt human subject research conducted or supported by DHHS or federal agencies that have adopted the Common Rule.

1.8 Research at the Medical School

Research at the medical school includes research meeting one or more of the following conditions:

- Conducted at, under the auspices of, or using the services or resources of the medical school.
- Conducted by or under the direction of any employee or agent of the medical school, including students, in connection with his/her medical school responsibilities.
- Conducted by or under the direction of any employee or agent, including students, of the medical school using any property or facility of the medical school.
- Involving the use of the medical school's non-public information to identify, contact, or study human subjects.

Even when the medical school IRB does not serve as the IRB of record, research conducted at, under the auspices of, or using the services or resources of the medical school is subject to quality monitoring and all other aspects and requirements of the medical school HRPP.

FDA regulations are oriented to the responsibilities of IRBs, investigators, and sponsors as opposed to institutions. In general, FDA-regulated research conducted in medical school facilities or by medical school Principal or Sub-Investigators (as defined on the FDA 1572 (or equivalent for medical device studies) or delegation of responsibilities log)

requires review by an IRB designated by the medical school. Exceptions to this requirement may be granted on a case-by-case basis (eg, when the medical school's involvement in the research is limited to the provision of a common diagnostic procedure and associated reading or analysis).

An IRB chair or Vice Chair, with the assistance of the HRPP director, IRB manager, and legal counsel as needed, determine whether the medical school is engaged in a particular research study. Investigators and other institutions may not independently determine whether the medical school is engaged in a particular research study.

When the medical school is engaged in research, the Institutional Official may choose to enter into an agreement to cede review to an external IRB.

Additional information on determining engagement is available in Guidance on Engagement on Institutions in Human Subjects Research from the DHHS OHRP.

1.9 Written Policies and Procedures

Medical school policies and procedures for Human Research Protection detail the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the medical school IRB. These policies and procedures are in this *Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Handbook*. This is not a static document. The policies and procedures are reviewed at least annually and revised as needed. The medical school dean, as the Institutional Official, approves all revisions of policies and procedures
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The HRPP director ensures that the research community is apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. Information is provided on the medical school website and distributed through electronic mailing lists. These policies and procedures are available on the medical school website and may be printed.

1.10 HRPP Structure

The HRPP encompasses individuals and committees with responsibilities for the protection of human subjects, and includes the Institutional Official, associate dean for Research, assistant dean for Research Compliance, HRPP director, HRPP/IRB staff, the IRB(s), Institutional Biosafety Committee, Sponsored Programs Administration staff, Research Integrity Officer, Chief Compliance Officer, clinical research staff, legal counsel, investigators, and others. The objective of this system is to assist the organization in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

The following officials, administrative units, and individuals have primary responsibilities for human subject protections:

1.10.1 Institutional Official

The ultimate responsibility of the HRPP resides with the medical school dean as Institutional Official of the program. The Institutional Official is legally authorized to represent the medical school and is the signatory of the FWA and assumes the obligations of the FWA. The Institutional Official is responsible for ensuring that the medical school HRPP and IRB(s) have the resources and support necessary to comply with all organizational policies, laws, and regulations that govern human subject research. Such resources include, but are not limited to:

- Staffing commensurate with the size and complexity of the research program.
- Appropriate office space, equipment, materials, and technology.
- Resources for the production, maintenance, and secure storage of HRPP and IRB records.
- Resources for auditing and other compliance activities and investigation of non-compliance.
- Access to legal counsel when required.
- Supporting educational opportunities related to human research protections for HRPP/IRB staff, IRB members, and investigators and research staff.

The Institutional Official conducts and documents an annual review of HRPP and IRB function, requirements, and resources and makes adjustments as needed.

The Institutional Official is also responsible for:

- Ensuring compliance with medical school policies and all applicable regulations for the protection of human subjects.
- Fostering, supporting, and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies.
- Oversight of the medical school IRB(s).
- Ensuring that the medical school IRB functions independently by, among other mechanisms, being directly accessible to the IRB chair(s) and members if they experience undue influence or if they have concerns about the function of the IRB(s).
- Ensuring that medical school IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations.
- Oversight over the conduct of research conducted by all medical school investigators.
- Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations.
- Oversight of the development and implementation of an educational plan for IRB members, staff and investigators.

The Institutional Official must complete OHRP Human Subject Assurance Training. The HRPP provides ongoing continuing education for the Institutional Official concerning human research protections.

The Institutional Official is made known to employees of the organization and is accessible by phone, email, in person, or other methods of communication. The IRB chair and HRPP director have access to the Institutional Official for any concerns or issues related to the HRPP.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to effectively administer the program. However, the Institutional Official is ultimately responsible and is expected to be knowledgeable about all human subject protections responsibilities at the organization.

1.10.2 HRPP Director

The HRPP director is selected by and reports to the assistant dean for Research Compliance, and is responsible for:

- Developing, managing, and evaluating policies and procedures that ensure compliance with all state, and federal regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing the administration of the IRB(s).
- Advising the Institutional Official on key matters regarding research conducted at, under the auspices of, or using the services or resources of the medical school.
- Implementing HRPP policies and procedures.
- Submitting, implementing, and maintaining an approved FWA through the Institutional Official and DHHS OHRP.
- Obtaining a copy of the FWA for any organization for which the medical school IRB serves as the IRB of record.
- Assisting investigators in their efforts to carry out the medical school's research in accordance with regulations and accepted standards.
- Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.
- Developing training requirements as required and as appropriate for investigators, subcommittee members and research staff, and ensuring that training is completed on a timely basis.
- Serving as the primary contact at the medical school for DHHS OHRP, FDA, and other federal regulatory agencies.
- Day-to-day responsibility for the operation of the HRPP and IRB, including supervision of HRPP/IRB staff.
- Responding to questions regarding the protection of human subjects.
- Working closely with the chair and vice chair of the IRB on the development of policy and procedures, as well as organizing and documenting the review process.

1.10.3 HRPP/IRB Staff

In addition to the leadership, support staff members for the HRPP and IRB include the IRB manager, IRB specialists, Research QA and Education Specialists, and Quality Coordinators. The medical school HRPP/IRB staff must comply with all ethical standards and practices. The duties and responsibilities for all staff are found in their respective position descriptions, and their performance is formally evaluated at least annually and as needed. HRPP/IRB staff report to the HRPP director who is responsible for day-to-day operations.

1.10.4 Institutional Review Board (IRB)

The medical school supports one or more IRBs with members that are appointed by the Institutional Official. The IRB prospectively reviews and makes decisions concerning all human research conducted at, under the auspices of, or using the services or resources of the medical school unless another IRB has been designated by the medical school to do so. The medical school IRB also provides IRB review and oversight for other local entities, the terms of which are described in IRB Services or Authorization Agreements executed prior to performing IRB review and oversight. The medical school IRB is responsible for the protection of rights and welfare of human subjects, through review and oversight of safe and ethical research. It discharges this duty by complying with the requirements of federal and state regulations, the FWA, and applicable organizational policies. (See Section 4 for a detailed discussion of the IRB.)

The IRB functions independently of, but in coordination with, other committees and officials with responsibilities related to human subject research. The IRB, however, makes its independent determination whether to approve or disapprove research based upon whether or not human subjects are adequately protected and regulatory requirements are satisfied.

Research that has been reviewed and approved by the IRB is subject to review and disapproval by officials of the medical school or organizations that rely upon the medical school IRB. However, those officials may not approve human research that has not been approved or has been disapproved by the IRB.

1.10.5 Legal Counsel

The medical school HRPP relies on the medical school's designated legal counsel for the interpretations and applications of state law and the laws of any other jurisdiction where research is conducted as they apply to human subjects research.

1.10.6 Department Chairs

For human subjects research conducted by medical school-employed investigators, the investigator's department chair, or designee, reviews the proposal before it is submitted to the IRB for review. Approval of the department chair, or designee, certifies that: (1) the investigators are appropriately qualified and possess the necessary credentials to

safely conduct the research and perform the protocol-required procedures; (2) the investigators have access to adequate facilities, staff, and equipment to perform the research; and (3) emergency or specialized care will be available, should the need arise.

When the medical school IRB serves as the IRB of record for human subjects research conducted by investigators who are not employed by the medical school, an appropriate leader recognized by the medical school and from the organization that does employ the investigators provides these same certifications

1.10.7 Investigators

The Principal Investigator for each study is ultimately responsible for the protection of the human subjects who participate in the research study. Investigators are expected to abide by the highest ethical standards when developing a protocol/research plan and ensuring that it incorporates the principles of The Belmont Report. Investigators are expected to conduct research in accordance with the IRB-approved protocol/research plan. Principal Investigators must oversee all aspects of the research by providing training and supervision of support staff, including oversight of the informed consent process. All subjects must give informed consent unless the requirement has specifically been waived by the IRB. Investigators must establish and maintain an open line of communication with research subjects within their responsibility. In addition to complying with all applicable policies and standards of regulatory bodies, investigators must comply with organizational and administrative requirements for conducting research. The investigator is responsible for ensuring that all research staff complete all organizational required training as well as training for their responsibilities in any given specific research study. When investigational drugs or devices are used, the investigator is responsible for providing a plan for their storage, security, dispensing, accounting, and disposal.

1.10.8 Sponsored Programs Administration

Sponsored Programs Administration staff review all research agreements with all sponsors including federal, foundation, and non-profit sponsors. This review ensures that all terms of the award (grant or contract) are in compliance with medical school policies. Sponsored Programs Administration reports to the assistant dean for Research Compliance, who has the authority to approve research proposals and to execute research agreements on behalf of the medical school.

Sponsored Programs Administration ensures that required AAHRPP language (see Section 20.2) is included in all contracts. Sponsored Programs Administration has access to the IRB submission to confirm that the contract and the consent documents are consistent in the description of costs to subjects and who pays in case of injury. Sponsored Programs Administration and HRPP/IRB staff coordinate efforts to ensure that all applicable individuals have filed appropriate conflict of interest and commitment disclosures to meet investigator conflict of interest and commitment policies.

A subaward (subcontract) must be executed between the medical school and collaborating institutions for grants and contracts that include human research activities that are conducted by investigators who are not employees of the medical school. The subaward includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and provide documentation of current and ongoing IRB approval. The collaborating institution must also ensure that key personnel involved in human subjects research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of education of key personnel to the medical school.

1.10.9 Center for Clinical Research

The Center for Clinical Research at the medical school offers a wide variety of services supporting the proper conduct of research at the medical school and at its clinical and community collaborators. Services are customized to match investigator needs and may include, but are not limited to, the following:

- Feasibility assessments.
- Protocol development.
- Recruitment planning.
- Consent form development.
- Regulatory document management.
- IRB submission support.
- Project management.
- Study coordinator services.
- Study visit management.
- Data entry and management.
- Specimen management including processing and shipping.
- Coordination with pharmacy, laboratory, radiology, and others.
- Liaison with sponsors, contract research organizations, and monitors.

1.11 Study-Specific Coordination

In addition to IRB approval, investigators must obtain and document the approval, support, or permission of other individuals, departments, and entities affected by the research as well as approval by other oversight committees, including, but not limited to:

- Sites where research activities will take place (eg, hospitals, outpatient clinics, physician practice offices, schools, community centers).
- Departments or units that will perform testing or provide services for the research (eg, pathology, pharmacy, radiology, nursing).
- Departments or units from which data will be requested (eg, medical records, registries and databases, registrar).
- Other medical school committees, as applicable (eg, Institutional Biosafety Committee).

For any that are indicated, a letter of support, collaboration, permission, or approval from the designated authority should be included in the Initial Study Application to the IRB. The application is reviewed by HRPP/IRB staff to ensure that all necessary letters from collaborators are included. The IRB may request review or consultation with any individual, department, committee, or entity even when such review or consultation is not specifically required by policy.

Other medical school committees and officials may not approve research involving human subjects to commence that has not been approved or has been disapproved by the IRB.